

# Respiratory Protection for Influenza

- Defining N95 Respirators and Masks
- IOM Studies on Respirators & Influenza
- What we know
- What we don't know: Research Needs
- Clinical Studies: Strengths and Weaknesses
- Summary

# Defining N95 Respirators for Healthcare Settings

- The term N95 is frequently used to describe a filtering facepiece respirator w/N95 filter
- NIOSH 42 CFR Part 84 defines the N95
- An N95 respirator is designed to protect the entire respiratory tract
- This respirator requires a tight seal to the face
- There are many models, some are FDA cleared

# Examples of N95 Respirators



# Defining Face Masks for Healthcare Workers

- Surgical or face masks are terms used to describe a loose fitting device worn over the nose and mouth
- Surgical masks are cleared by FDA for sale under their 510-K approval process (e.g. breathing & flame resistance, filter efficiency)
- Other face masks (e.g. dental masks) may not be cleared by FDA
- Masks were designed to protect patients/surgical area from healthcare worker

# Defining Face Masks for Healthcare Workers (2)

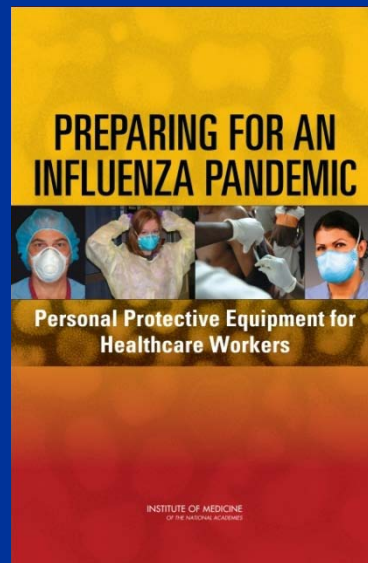
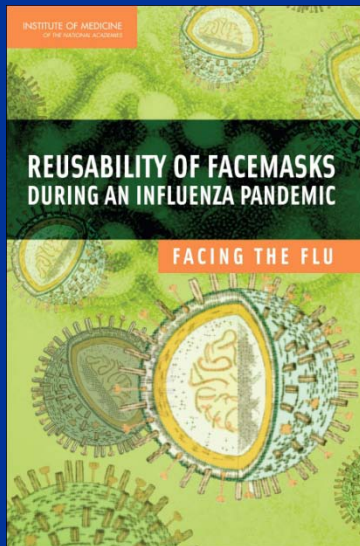
- Masks are defined as PPE under OSHA's Blood Borne Pathogen standard and CDC seasonal influenza guidelines
- Masks may provide limited protection to the upper respiratory tract





# IOM Studies on Respirators and Masks for Influenza and Healthcare Workers

- Three studies completed and a fourth just completed to be discussed by Bill Kajola
- Studies have been supported by DHHS, CDC and NPPTL



# Reusability of Face Masks During an Influenza Pandemic (2006)

## ■ Key Findings:

- No simple way to decontaminate N95 respirator
- No simple way to eliminate fit testing of N95
- No documented way to decontaminate masks

## ■ Key Recommendations

- Avoid contaminating surface of respirator to extend its life
- Conduct research to disinfect respirators & masks
- Determine routes of exposure and risks

# Preparing for an Influenza Pandemic: PPE for Healthcare Workers (2008)

## ■ Key Recommendations:

-Define evidence-based performance requirements:

function (e.g. effectiveness)

usability (e.g. accommodate range of faces)

comfort & wearability

maintenance & reuse

cost

aesthetics

durability



# Preparing for an Influenza Pandemic: PPE for Healthcare Workers (2008)

- Key Recommendations (continued):
  - Research on design & engineering for next generation of PPE
  - Establish measures to assess and compare effectiveness of PPE
  - Strengthen pre and post-market testing and evaluation of PPE
  - Expand research and resources for PPE research

# Respiratory Protection For Healthcare Workers Against Novel H1N1 Influenza A (2009)

## Recommendations

- (1) Use fit-test N95 respirators
  - Endorsed CDC Guidelines at the time
  - Employers should ensure respirators used in accordance with OSHA regulations
- (2) Increase research on influenza transmission and respiratory protection
  - Explore effectiveness of respiratory protection in clinical trials
  - Design next generation to enhance safety, comfort

# What We Know

## Particle Penetration Through Filters

- N95 filters will stop 95% of the most penetrating particles (and often 97-99%)
- N95 filters will stop particles the size of virions
- Masks have a wide range of filter efficiencies ranging from 0-90% against small aerosols

# What We Know

## The Protection Afforded by Respirators Is Governed by Fit

- NIOSH certification of N95 respirators does not include the quality of the fit
- Any specific N95 respirator model cannot fit all the sizes of faces found in the workforce
- Some higher priced respirator models have facial seal enhancements
- Purchasers generally cannot determine the quality of the fit of respirators they buy

# What We Know

- Respirator fit test methods are cumbersome, complicated and may discourage some employers from choosing to purchase a respirator
- Current respirator models (including PAPRs) are not well designed for healthcare workers in terms of: comfort, tolerability, communication
- Masks will not protect the entire respiratory tract against airborne viruses due to their lack of sealing to the face

# What We Don't Know

- The modes of transmission of influenza for different work activities
  - can masks and respirators enhance protection just from fomites
  - can an infectious dose result from airborne influenza
- Can masks provide protection against large droplet-size aerosols (both filter performance and facepiece leakage)



# What We Don't Know

- Is eye protection important for non-aerosol generating work
- Can face shields provide alternative protection to masks for influenza
- Does the surface of respirators and masks provide a fomites source:
  - Are anti-viral coatings useful protection
  - Can decontamination methods be developed
- How long should a mask or respirator be used during a pandemic

# What We Don't Know

- Do face masks provide protection to the patient when worn by workers?
- Do face masks worn by patients provide protection to workers?
- Do respirators worn by workers provide enhanced protection to patients?

# Clinical Studies of Respirators and Face Masks

## Background

- Infectious disease professionals and epidemiologists seek clinical evidence that respirators provide superior protection to face masks
- Clinical trials and research are typically performed to determine the benefit of therapy or controls (e.g. vaccination)
- There is no clinical evidence that wearing face masks provide protection to healthcare workers, yet they are recommended by CDC for close contact with patients suspected of having influenza.

# Clinical Studies of Respirators and Face Masks

## Background

- Neither clinical studies nor surveillance data are generally available for workers who use PPE
- There are some limited data on workers using respirators and participating in biological monitoring programs for some contaminants (e.g. fluoride, lead, mercury). These are not surveillance of disease studies but dose measurements
- Any study examining outcome data (surveillance) for PPE does so in the context of a program (e.g. training), and the results may not be applicable to other less complete programs.

# Clinical Studies of Respirators and Face Masks

- Clinical studies of respirators and masks cannot determine the transmission routes of influenza, because of exposures outside of the workplace.
- Clinical studies may be able to determine the relative effectiveness of using respirators versus masks for protection against influenza.

# Clinical Studies of Respirators and Face Masks

## Major Challenges of Clinical Studies

- PPE is likely to be worn only during a portion of the potential exposure: community and family exposures may have an important exposure role
- PPE compliance may be inconsistent
- Since N95 respirators and masks come in a variety of models, results may not be generalizable to other models



# Clinical Studies of Respirators and Face Masks

## Major Challenges of Clinical Studies

- It is likely that no true control population can be used due to bioethics. Therefore, it may be difficult to determine if either respirators or masks are efficacious
- Small differences in outcome results (below statistical significance) may have significant overall importance to risk of patients and workers given the large number of users of respirators and masks
- Despite challenges, clinical studies should be conducted and other studies should be done to support these results (e.g. surveillance data on healthcare workers)

# Clinical Studies of Respirators and Face Masks

## Clinical Trials

- The Loeb study from Canada:
  - no difference in workers exposed to influenza between those who wore face masks and those wearing respirators
  - however, those who reported ILI were more likely to be wearing face masks than respirators.
- The CDC/NIOSH, VA and Johns Hopkins study:
  - multi year study to examine differences in infectious respiratory disease rates and ILI among those wearing masks and respirators

# Summary

- The transmission route(s) of influenza is the most important piece of information needed to determine PPE requirements
- Clinical studies and surveillance data are needed to determine the risk of transmission to workers and patients and the effectiveness of PPE
- Better respirators are needed that meet the needs of workers: comfort, tolerability, and communication
- Simpler fit test methods are needed to encourage the use of respirators, when they are required